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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,503	06/07/2001	Hiroshi Oda	11283-009001	1563

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/05/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,503

Applicant(s)

ODA ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2,6-12,14 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1641

DETAILED ACTION

Status of the claims

The amendment filed on June 10, 2002 is acknowledged and has been entered.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 3-5, 13, and 15-17 in Paper No. 11 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 9, lines 21-22 in the specification, Applicant discloses a body fluid sample is taken from a subject. And in the examples the applicant discloses that the sample is taken from patients who were normal in both serum creatinine concentration and urinary albumin index but abnormal in serum L-PGDS concentration. The applicant does not disclose a subject who substantially appears not to have any renal diseases. There is no description in the specification disclosing that the subject substantially appears not to have any renal diseases. Further, the specification fails to distinguish between healthy and normal subjects and subjects who substantially appear not to have any renal diseases. Even

Art Unit: 1641

though the method appears to be a method of differential diagnosis it is not recited as such.

3. Claims 13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 9, lines 21-22 in the specification, Applicant discloses a body fluid sample is taken from a subject. And in the examples the applicant discloses that the sample is taken from patients who were normal in both serum creatinine concentration and urinary albumin index but abnormal in serum L-PGDS concentration. The applicant does not disclose a subject who is substantially asymptomatic of renal diseases. There is no description in the specification disclosing that the subject is substantially asymptomatic of renal diseases. Further, the specification fails to distinguish between healthy and normal subjects and subjects who substantially appear not to have any renal diseases. Even though the method appears to be a method of differential diagnosis it is not recited as such.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-5, 13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1641

Claim 1, line 3 "substantially" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What degree is substantially not having any renal diseases.

Claim 1, line 3 "appears not to have any renal diseases" is vague and indefinite. It is unclear how subject appears not to have any renal disease (i.e. Does applicant physically appear, medically appear, or by laboratory appearance).

Claim 4 is vague and indefinite because it is not related to a method step, only to an analysis step.

Claim 5 is vague and indefinite because it is not related to a method step, only to an analysis step.

Claim 13 is vague and indefinite because the body of the claim does not correlate with the preamble. It is unclear what the correlation is between early-stage renal abnormality and a subject who is substantially asymptomatic of renal disease.

Claim 13, line 3 "subject who is substantially asymptomatic of renal disease. It is unclear how the subject is asymptomatic (i.e. Lack of fever, lack of glomerular lesions, negative for specific laboratory test).

Claim 16 is vague and indefinite because it is not related to a method step, only to an analysis step.

Claim 17 is vague and indefinite because it is not related to a method step, only to an analysis step.

Art Unit: 1641

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 13 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffman et al (Molecular characterization of Beta-trace protein in human serum and urine: a potential diagnostic marker for renal diseases, Glycobiology, Vol 7, no. 4, p 499-506 (1997)).

Hoffman et al disclose that beta-trace protein (lipocalin-type prostaglandin D synthase (L-PGDS)) was isolated from cerebrospinal fluid, serum, plasma and urine samples of normal volunteers and sera and hemofiltrate of patients with chronic renal failure (abstract). Hoffman et al disclose that serum L-PGDS concentration in patients with end-stage renal failure increased as compared to the L-PGDS of the normal volunteers. Hoffman et al disclose that serum beta-trace (L-PGDS) concentrations were determined by quantitative immunoaffinity chromatography in conjunction with amino acid sequencing and SDS gel electrophoresis and revealed a broad range of concentrations (p. 504, col 2, lines 36-60).

Even though Hoffman et al is silent on a method of detection of an early-stage renal disease, Hoffman et al teaches that beta-trace protein (L-PGDS) accumulates more significantly in serum in pathological conditions than other proteins in current use

Art Unit: 1641

and that the beta-trace protein may be used for the study and early diagnosis of renal diseases (p. 505, lines 14-21). Therefore, it would have been obvious to one of ordinary skill in the art to have a reasonable expectation of success to use the method of Hoffman et al for the detection of early-stage renal disease.

Response to Arguments

Applicant's arguments filed June 10, 2002 have been fully considered but they are not persuasive.

Applicant argues that the Hoffman et al reference demonstrates that a high level of L-PGDS correlates with end-stage renal failure and that it does not show or disclose that a high level of L-PGDS correlates with the early-stage of renal disease. This is not found persuasive because since, Hoffman et al teaches that beta-trace protein (L-PGDS) accumulates more significantly in serum in pathological conditions than other proteins in current use and that the beta-trace protein may be used for the study and early diagnosis of renal diseases (p. 505, lines 14-21). Therefore, it would have been obvious to one of ordinary skill in the art to have a reasonable expectation of success to use the method of Hoffman et al for the detection of early-stage renal disease. Further, there is no recitation in the claims that a high level of L-PGDS correlates with the early-stage of a renal disease. Therefore, it is the Examiner's position that the Hoffman et al reference still reads on the claims as recited.

Conclusion

No claims are allowed.

Art Unit: 1641

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Art Unit: 1641



Gary W. Counts
Examiner
Art Unit 1641
November 4, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/04/02